

DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

2831. Misbranding of female hormones. U. S. v. 2 Boxes * * *. (F. D. C. No. 27161. Sample No. 57787-K.)

LABEL FILED: April 26, 1949, Southern District of California.

ALLEGED SHIPMENT: The product was shipped on or about December 13 and 27, 1948, from Summit, N. J., to San Francisco, Calif., and was reshipped on or about February 3, 1949, from San Francisco to Long Beach, Calif.

PRODUCT: 2 boxes of *female hormones* at Long Beach, Calif., in possession of the Hudson Products Co. The product was repackaged from goods shipped to this company.

LABEL, IN PART: "Female Hormones 30 0.02 mg. Tablets of Ethinyl Estradiol * * * For use when Ethinyl Estradiol is indicated for symptoms of female hormone deficiency. Suggested dosage: 0.02 mg. tablets two or three times daily until relieved * * * Caution: Take only as directed."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use; Section 502 (f) (2), the labeling of the article failed to bear such adequate warnings against use in those pathological conditions where its use may be dangerous to health and against unsafe dosage and duration of administration, in such manner and form as are necessary for the protection of users, since the article contained ethinyl estradiol and its labeling failed to warn that use of the article may stimulate early or incipient cancer of the breast and genital system and may induce uterine bleeding; and, Section 502 (j), the article, by reason of its ethinyl estradiol content, was dangerous to health when used in the dosage and with the frequency and duration recommended in its labeling. The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: May 26, 1949. Default decree of condemnation and destruction.

2832. Misbranding of mineral oil. U. S. v. 72 Bottles * * *. (F. D. C. No. 27188. Sample No. 46141-K.)

LABEL FILED: May 6, 1949, Southern District of Iowa.

ALLEGED SHIPMENT: On or about February 24, 1949, by the Halitosine Co., from St. Louis, Mo.

PRODUCT: 72 1-pint bottles of *mineral oil* at Keokuk, Iowa.

LABEL, IN PART: "Domino Mineral Oil U. S. P. Extra Heavy * * * Directions * * * Infants * * * ½ teaspoonful * * * Prepared by Domino Products Co. St. Louis, Mo.—Dallas, Texas."

NATURE OF CHARGE: Misbranding, Section 502 (f) (2), the article failed to bear such adequate warnings against use by children where its use may be dangerous to health and against unsafe dosage and methods and duration of administration, in such manner and form as are necessary for the protection of users. The labeling of the article failed to warn that the article should not be taken at any time other than bedtime or administered to infants except on advice of a physician.

Further misbranding, Section 502 (j), the article was dangerous to health when used in the dosage and with the frequency and duration prescribed,